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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/005,711	01/12/98	BROCIA R	

HM22/0204

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EXAMINER	
GITOMER,R	
ART UNIT	**PAPER NUMBER**
1623	16

DATE MAILED: 02/04/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/005,711	Applicant(s) Brocia
	Examiner Ralph Gitomer	Group Art Unit 1623

☒ Responsive to communication(s) filed on *Jan 4, 1999* .

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *12-22* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *12-22* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *3*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

The IDS and amendment received 1/4/98 have been entered and claims 12-22 are currently pending in this application. The examiner requests information regarding related cases to this case. 08/496,806 is currently pending, 08/543,117 has been abandoned and file wrappered to 08/932,517, 09/005,875 is pending. The examiner requests information of how each of these cases relates to the present application.

Claims 12-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Many of the limitations in the newly added claims appear to be new matter. For example, in claim 21 "and not cholesteryl esterase" is not found in the specification as originally filed. Applicant is requested to point out where in the specification as originally filed enablement is found for each feature in the claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

Claims 12-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Brocia.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Brocia (5,770,355) with a 102(e) date of 10/29/1993 teaches the same invention as presently claimed.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 12-22 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-36 of prior U.S. Patent No. 5,770,355. This is a double patenting rejection.

The present claims, as written, encompass the same inventions as claimed in '355.

Claims 12-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The application as originally filed does not enable the newly submitted claims which appear to be directed to an assay with some fluorescent component. It would appear there is a chemical reaction cascade involved in the invention but none is shown. The acronyms are not clear and are inconsistently applied. Note page 9 last full paragraph, such a method is not understood in context. On page 10 second paragraph last line, it is not seen CETP mass is measured. On page 11 last paragraph, "the normalization factor includes a colorizing factor that reacts in response to the normalizing factor of choice." The example on page 12 is insufficiently detailed to follow. No data

of any sort nor results of any determination are found in the specification. As written, one of skill in this art could not perform the claimed invention by following the teachings of the specification.

Claims 12-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for the following terms. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In claim 12 and all occurrences, the terms "an activity dependent light emission intensity component," and "a substrate concentration dependent light emission intensity quenching component" lack enablement as it would require one of ordinary skill in this art undue experimentation to determine which such component would work in the instant invention.

The entire scope of the claims has not been enabled because:
1. Quantity of experimentation necessary would be undue because of the large proportion of inoperative compounds claimed.
2. Amount of direction or guidance presented is insufficient to predict which substances encompassed by the claims would work.
3. Presence of working examples are only for specific substances and extension to other compounds has not been specifically taught or suggested.

4. The nature of the invention is complex and unpredictable.

5. State of the prior art indicates that most related substances are not effective for the claimed functions.

6. Level of predictability of the art is very unpredictable.

7. Breadth of the claims encompasses an innumerable number of compounds.

8. The level of one of ordinary skill in this art is variable.

In re Wands, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)

Claims 12-22 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are not in condition for proper examination and a proper search is impossible. Further, there may be double patenting issues over other applications but this cannot be determined at this time.

The rewritten claims are not understood and do not appear to be directed to the specification as originally filed. For example, "said light emission intensity represents said measurement of said enzyme activity" is not understood. In claim 21 "CETP" all acronyms should be spelled out in the first occurrence in the claims. In general, the claims lack antecedent basis and have inconsistent tenses so they cannot be properly interpreted.

The title of the invention is not aptly descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The disclosure is objected to because of the following informalities: The headings in the specification are nonstandard, for example, no Brief Description of the Drawings are found. There are sufficient typographical errors in the specification, including inexplicable brackets, to affect the meaning of the writing. Note no amendment can include brackets to amend the specification whicb contains brackets. Appropriate correction is required.

The following prior art pertinent to applicant's disclosure is made of record and not relied upon: Foulkes (5,846,720) teaches modulating genes.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS

of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm. The examiner can also be reached on alternate Mondays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marian Knode, can be reached on (703) 308-4311. The fax phone number for this Art Unit is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1234.

Ralph Gitomer
Primary Examiner
Group 1623

RALPH GITOMER
PRIMARY EXAMINER
GROUP 1200